K101567

SEP 2 2010

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: June 7, 2009

1. Company and Correspondent making the submission:

Name – Cixi Leinuo Plastic Co., Ltd

Address – No. 56, Luoming South Road, Guanhaiwei Town, Cixi , Ningbo, Zhejiang, China,315316

Telephone – +86-574-63673001

Fax – +86-574-63671001

Contact – Mr. Leiping Wang

Email – cxleinuo@163.com

2. Device :

Trade/proprietary name: Sharps Container Lns-T1

Common Name : Sharps Container

Classification Name : Container, Sharps

Predicate Devices:

Model	Manufacturer	K Number	Submitted Device
Sharps Away Disposable Containers	Solutions, Inc.	K072667	Lns-T1

3. Classifications Names & Citations :

21CFR 884.6120, MMK, Sharps Container, Class II

4. Description :

4.1 General

The Sharps Container is a piece of equipment used in hospitals, physicians' offices, dental offices, laboratories, home health areas, patient rooms and other locations of medical waste. The sharps container is designed to safely contain used needles or syringes and prevent accidental needle sticks from used syringes or needles.

Structure

- The device is made of injected molded polypropylene material. The material is made of molded plastic into a specific shape. The actual shape is designed to sit on the floor or a desk.
- On the outer casing of all the sharps containers is the Biohazard Warning label in Orange, noticeably displayed.
- The molded plastic container is designed and manufactured such that there will be no leakage during storage, handling or transport.

Please refer to the table below for the device thickness:

Model Name	Size (cm)	Volume (L)	Empty Weight (grams)	Thickness of material
LNS-T1	**10.5*8*18**	**1.0**	**80g**	**body:1.2mm lid:1.3mm**

5. Indication for use :

Device Name:

Lns-T1

Indications for Use:

The sharps container are intended to be used in healthcare facilities, including nursing stations, medication carts, laboratories, dental offices, emergency rooms, surgical rooms, treatment rooms, emergency vehicles, veterinarian office and other small quantity waste generators for the safe disposal of hazardous sharps.

6. Comparison with predicate device :- Please see the next page

Element of comparison	Subject Device	Claimed SE Device
Company	Cixi Leinuo Plastic Co., Ltd.	Solutions Inc.
FDA510(K) Number	N/A	K072667
Device Name	Sharps Container	Sharps Away Disposable Container
Intended use(s)	Leinuo sharps containers are intended to be used for the safe disposal of hazardous sharps.	Sharps Away Disposable Containers are intended to be used for the safe disposal of hazardous sharps.
Target Population	Healthcare professional	Healthcare professional
where used: Hospital, Physicians offices, Dental offices, Laboratories, Home health, Patient room, etc.	Yes	Yes
Material	Polypropylene	Polypropylene
Sharps closure	Flaps are closed and locked in place for removal	Flaps are closed and locked in place for removal
Impact Resistance	Yes	Yes
Puncture Resistance	Yes	Yes
Leak Resistance	Leak-proof on the sides and bottom	Leak-proof on the sides and bottom
Single Use	Yes	Yes

7. Performance Testing :

   Mechanical, environmental safety and performance testing have been accomplished according to BS7230:1990, ASTM F2132:2008 and OSHA 29CFR1910. The product passed all tests. These tests demonstrate this product is substantially equivalent to the predicate device.

8. Conclusions:

   In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification The Cixi Leinuo Plastic Co., Ltd. Sharps Container, Model Lns-T1 is substantially equivalent to the predicate devices as described herein.

9. Cixi Leinuo Plastic Co., Ltd will update and include in a summary any other information deemed reasonably necessary by the FDA.

END

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Cixi Leinuo Plastic Company, Limited
C/O Mr. Charles Mack
IRC
77325 Joyce Way
Echo, Oregon 97826

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Re: K101567
Trade/Device Name: Sharps Container, Models Lns-T1
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: MMK
Dated: March 25, 2010
Received: June 4, 2010

Dear Mr. Mack:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K101567

Indications for Use

Device Name:
Sharps Container, Models Lns-T1
Indications For Use:

The sharps container are intended to be used in healthcare facilities, including nursing stations, medication carts, laboratories, dental offices, emergency rooms, surgical rooms, treatment rooms, emergency vehicles, veterinarian office and other small quantity waste generators for the safe disposal of hazardous sharps.

Prescription Use _____ AND/OR Over-The-Counter Use ___√___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K101567